

**RULES OF
DEPARTMENT OF COMMUNITY HEALTH
HEALTHCARE FACILITY REGULATION**

AMEND CHAPTER 290-9-9

AND

REPLACE WITH NEW CHAPTER 111-8-22

**RULES AND REGULATIONS FOR END STAGE RENAL DISEASE
FACILITIES**

SYNOPSIS OF PROPOSED RULE CHANGES

STATEMENT OF PURPOSE: The Department of Community Health proposes to amend the Rules for End Stage Renal Disease Facilities by replacing the Chapter number, 290-9-9 with a new Chapter number, 111-8-22. This change is necessary to reflect that end stage renal disease facilities are subject to regulation by the Department of Community Health rather than the Department of Human Resources, which has since been renamed as the Department of Human Services. These rules are being proposed pursuant to the authority granted the Department of Community Health in O.C.G.A. §§ 31-2-4, 31-2-5, 31-2-7 and 31-44-1 et seq.

In the formulation of the proposed new rules, the Department has considered the economic costs associated with the regulations and the impact on small businesses in the state. To the extent possible, the proposed rules do not impose excessive regulatory costs on the regulated entities while supporting the quality of care being delivered and the health and safety of the participants receiving care.

MAIN FEATURES OF THE PROPOSED RULES: The proposed Rules for End Stage Renal Disease Facilities, Chapter 111-8-22, set forth the existing standards for licensure as a dialysis facility authorized to provide renal dialysis services. These proposed rules do not change the existing dialysis rules except to replace the Chapter number, the name of the Department, correct rule numbering errors and update legal references throughout. The proposed rules include the following features:

- Restatement of existing Purposes of This Chapter in Rule 111-8-22-.01.

- Substitution of the Department of Community Health for the Department of Human Resources in the definition of the Department and the restatement of all existing Definitions in Rule 111-8-22-.02
- Restatement of existing License Requirements and Exemptions in Rule 111-8-22-.03.
- Restatement of existing provisions for Application for a License and License Renewal, correction of numbering sequence and deletion of reference to amount of application fee in Rule 111-8-22-.04.
- Restatement of existing provisions for Facility Inspections in Rule 111-8-22-.05.
- Restatement of existing provisions for Facility Organization and Administration and correction of numbering sequence in Rule 111-8-22-.06.
- Restatement of existing requirements for Facility Communication Responsibilities and correction of numbering sequence in Rule 111-8-22-.07.
- Restatement of existing requirements for Continuous Quality Improvement and correction of numbering sequence in Rule 111-8-22-.08.
- Restatement of existing requirements for Medical Staff and Medical Services in Rule 111-8-22-.09.
- Restatement of existing requirements for Staff Qualifications, Training, and Supervision and Staff Records and correction of rule reference and numbering sequence in Rule 111-8-22-.10.
- Restatement of existing requirements for Patient Care Services in Rule 111-8-22-.11.
- Restatement of existing provisions for Patient Care Plans in Rule 111-8-22-.12.
- Restatement of existing provisions for Hemodialyzer Reuse and correction of numbering sequence in Rule 111-8-22-.13.
- Restatement of existing provisions for Medical Records in Rule 111-8-22-.14.
- Restatement of existing requirements for Environment of Care in Rule 111-8-22-.15.
- Restatement of existing requirements for Infection Control in Rule 111-8-22-.16.
- Restatement of existing requirements for Emergency and Disaster Preparedness in Rule 111-8-22-.17.
- Restatement of existing requirements for Requests for Waiver or Variance and correction of numbering sequence in Rule 111-8-22-.18.
- Restatement of existing requirements for Enforcement of Rules and Regulations and correction of numbering sequence in 111-8-22-.19.
- Restatement of existing requirements for Severability of These Rules in Rule 111-8-22-.20.
- Inclusion of updated references to the Official Code of Georgia Annotated throughout and cross-references to other rules.

**RULES
OF
DEPARTMENT OF ~~HUMAN RESOURCES~~ COMMUNITY HEALTH
OFFICE OF REGULATORY SERVICES HEALTHCARE FACILITY
REGULATION**

**CHAPTER 290-9-9111-8-22
END STAGE RENAL DISEASE FACILITIES**

TABLE OF CONTENTS

<u>290-9-9111-8-22</u> -.01	Purposes of This Chapter
<u>290-9-9111-8-22</u> -.02	Definitions
<u>290-9-9111-8-22</u> -.03	License Requirements and Exemptions
<u>290-9-9111-8-22</u> -.04	Application for a License and License Renewal
<u>290-9-9111-8-22</u> -.05	Facility Inspections
<u>290-9-9111-8-22</u> -.06	Facility Organization and Administration
<u>290-9-9111-8-22</u> -.07	Facility Communication Responsibilities
<u>290-9-9111-8-22</u> -.08	Continuous Quality Improvement
<u>290-9-9111-8-22</u> -.09	Medical Staff and Medical Services
<u>290-9-9111-8-22</u> -.10	Staff Qualifications, Training, and Supervision and Staff Records
<u>290-9-9111-8-22</u> -.11	Patient Care Services
<u>290-9-9111-8-22</u> -.12	Patient Care Plans
<u>290-9-9111-8-22</u> -.13	Hemodialyzer Reuse
<u>290-9-9111-8-22</u> -.14	Medical Records
<u>290-9-9111-8-22</u> -.15	Environment of Care
<u>290-9-9111-8-22</u> -.16	Infection Control
<u>290-9-9111-8-22</u> -.17	Emergency and Disaster Preparedness
<u>290-9-9111-8-22</u> -.18	Requests for Waiver or Variance
<u>290-9-9111-8-22</u> -.19	Enforcement of Rules and Regulations
<u>290-9-9111-8-22</u> -.20	Severability of These Rules

290-9-9111-8-22-.01 Purposes of This Chapter.

These rules and regulations establish minimum standards for the operation of end stage renal disease facilities in order to ensure the health, safety, and protection of the patients served, and establish procedures and requirements for the licensing of such facilities.

Authority O.C.G.A. Secs. 31-2-4, 31-2-5, 31-2-7 and 31-44-3. **History.** Original Rule entitled "Purposes of This Chapter" adopted. F. Dec. 6, 2001; eff. Dec. 26, 2001.

Chapter 111-8-22, Proposed Rules for End Stage Renal Disease Facilities
Presented to BCH for Initial Adoption 11/08/12

Page 3 of 51

290-9-9111-8-22-.02 Definitions.

Unless another meaning is specifically indicated by context, these selected terms shall have the following definitions when used in these rules and regulations:

(a) Applicant means a person, business entity, corporation, partnership or association applying for a license to operate an end stage renal disease facility in Georgia;

(b) Department means the Department of ~~Human Resources~~Community Health of the state of Georgia;

(c) Dialysis means a process by which dissolved substances are removed from a patient's body by diffusion, osmosis, and convection (ultrafiltration) from one fluid compartment to another across a semi-permeable membrane;

(d) Dialysis technician means an individual who is not a registered nurse or physician and who provides dialysis care under the supervision of a registered nurse or physician;

(e) End stage renal disease means that stage of renal impairment that appears irreversible and permanent and that requires a regular course of dialysis or kidney transplantation to maintain life;

(f) End stage renal disease facility means a facility that provides dialysis treatment, home dialysis training, and support services, or any combination of such services, to individuals with end stage renal disease;

(g) Equipment technician means an individual who performs the required tasks for the maintenance, monitoring, and repair of dialysis, reuse processing, and water treatment systems and equipment at the facility;

(h) Facility means an end stage renal disease facility;

(i) Healthcare personnel means any person providing healthcare services directly to patients at the facility, including but not limited to the provision of medical or nursing care;

(j) Initial license means the first license issued by the Department for a particular end-stage renal disease facility, with subsequent licenses requiring review for renewal;

(k) Nurse responsible for nursing services means the Georgia licensed registered nurse who has at least 12 months of experience in clinical nursing, and an additional 6 months of experience in nursing care of the patient with permanent kidney failure or undergoing kidney transplantation, including training in and experience with the dialysis process or has 18 months of experience in nursing care of the patient on maintenance

dialysis, or the nursing care of the patient with a kidney transplant, including training in and experience with the dialysis process. Where the nurse responsible for nursing services is also in charge of self-care dialysis training, at least 3 months of the total required dialysis experience is in training patients in self-care;

(l) **Physician** means an individual who is licensed to practice medicine in Georgia under O.C.G.A. Chapter 43-34;

(m) **Preceptor** means an individual who provides direct supervision of the provision of patient care by trainees who are in the process of completing training as dialysis technicians, and who:

1. Is a licensed nurse or a dialysis technician with at least twelve months experience in hemodialysis, and

2. Has authorization from a supervising nurse or the medical director of the facility to be preceptor;

(n) **Reuse technician** means an individual who is not a registered nurse or licensed physician who performs the procedures necessary to clean and properly prepare kidney dialyzers for use for multiple treatments;

(o) **Special purpose facility** means an end stage renal dialysis facility providing dialysis services at special locations on a short-term basis to a group of dialysis patients who would otherwise be unable to obtain treatment in that special location; and

(p) **Temporary provisional license** means a license to provide end stage renal care for patients for a limited time period, not to exceed six months.

Authority O.C.G.A. Sec. 31-44-1. **History.** Original Rule entitled “Definitions” adopted. F. Dec. 6, 2001; eff. Dec. 26, 2001.

290-9-9111-8-22.-03 License Requirements and Exemptions.

(1) **License Requirements.** Unless specifically exempted under 290-9-9111-8-22-.03(2), no person, business entity, association, partnership, or corporation shall operate an end stage renal disease facility in Georgia without having first obtained a license from the Department.

(a) A license issued by the Department is required prior to the initiation of dialysis or dialysis support services for patients.

(b) A facility is required to have a separate license for each physical address. Separate applications and licenses are required for facilities maintained separately, even if they are owned or operated by the same person(s), business, partnership, or corporation, and may be doing business under the same trade name.

|(c) The license shall be effective for twelve (12) months following the date of issue; the temporary provisional license shall be effective for a maximum of six (6) months. If the facility applies for renewal as required by these regulations, the existing license shall remain in effect until the inspection for renewal is completed.

|(d) The facility license is not transferable. A new license is required for any change in physical location, operational or trade name, or facility ownership. An application for a new license must be submitted at least 30 days prior to the change. The former license shall be considered revoked upon issuance of the new license, and shall be returned to the Department.

|(e) The facility license shall be prominently displayed in a public area of the facility at all times of operation.

|(f) If the facility anticipates that it will close or cease to operate, the governing body shall notify the Department and the patients at least thirty (30) days prior to the anticipated date of closure.

|_1. With the notification of intent to close, the facility shall submit a written plan for the orderly transfer of care of the facility's patients and their clinical records.

|_2. Upon closure, the facility shall return the existing license to the Department. The license shall be considered revoked, unless the facility has been placed on temporary inactive status as described in these rules.

|_(2) **Exempt Facilities.** The following facilities are not required to have a license:

|(a) Any hospital permitted under O.C.G.A. 31-7 as a hospital that provides dialysis to individuals receiving services from the hospital;

|(b) The office of a physician unless the office is used primarily as an end stage renal disease facility; and

|(c) Federal or state agency facilities.

|(d) Non-profit camps operating for eight (8) days or less which do not charge a fee to the campers or their families and which provide dialysis services through the use of staff who possess the same minimum qualifications as required of staff providing services under these rules.

Authority O.C.G.A. Sec. 31-44-5. **History.** Original Rule entitled "License Requirements and Exemptions" adopted. F. Dec. 6, 2001; eff. Dec. 26, 2001.

290-9-9111-8-22.04 Application for a License and License Renewal.

_(1) All applications for licenses shall be submitted on forms provided by the Department.

_(2) No application shall be considered by the Department unless it is complete, and is accompanied by all required attachments and fee payments.

_(3) The Department shall issue an annual license to an applicant if it is determined that the applicant and the facility meet the requirements of these rules.

_(4) Initial License.

_(a) **Application for Initial License.** The application for the initial license shall be submitted to the Department not later than thirty (30) days prior to the anticipated date of the opening and initiation of operations by the facility, shall be signed by the executive officer of the facility's governing body, and shall be accompanied by:

_1. The nonrefundable ~~\$100.00~~ application fee;

_2. The initial license fee as designated on the fee schedule;

_3. A narrative description of the services to be offered at the facility, including the number of dialysis stations;

_4. The name and contact information of the facility administrator as appointed by the facility's governing body;

_5. Evidence that the facility has sufficient staff, qualified as required by these regulations, to meet the needs of patients, with a description of the organizational structure of the staffing; and

_6. Proof of facility ownership:

_(i) If ownership is a corporation, the application shall be accompanied by a copy of the Certificate of Existence (Good Standing) from the Office of the Secretary of State of Georgia.

_(ii) If the facility is non-profit, the application shall be accompanied by legal proof of the organization and the names and addresses of all trustees.

_(iii) If ownership is neither a corporation nor a non-profit organization, the name and address of each person with ownership in the facility shall be submitted with the application.

(b) Temporary Provisional License. The Department may at its discretion issue a temporary provisional license to the facility. The temporary provisional license shall be effective for a period of no more than six (6) months.

1. A temporary provisional license shall be considered for only the following situations:

(i) The facility has applied for an initial license or renewal of a license and cannot demonstrate full compliance with these rules, but has demonstrated satisfactory evidence that it is making progress toward meeting these rules and has submitted an acceptable plan of correction; or

(ii) The facility has applied for a license in order to function as a special purpose facility, meeting the requirements of these rules, with intended operation of no more than the six-month period of effectiveness of the license.

2. A temporary provisional license may be issued by the Department only when the facility has demonstrated sufficient compliance with these rules that the health and safety of patients will not be endangered.

3. A 12-month license issued during the period of temporary provisional licensure shall not require an additional license fee.

(c) An end stage renal disease facility in operation at the time these rules initially become effective, and holding certification for participation in the federal Medicare program, shall be granted an initial license upon payment of the applicable license fee, without requiring inspection. This initial license shall be effective for a period of twelve (12) months, unless suspended or revoked as a result of an adverse action, and shall be subject to the renewal process.

(5) Application for a New Annual License Due to Change in Facility Name, Facility Location, or Facility Ownership.

(a) At least 30 days prior to the change in the facility's name, location, or ownership, a new application for license shall be submitted which shall contain the new name, location, proof of ownership, any changes in the official mailing address and contact telephone numbers, and a description of any organizational changes or changes in key personnel.

(b) The Department, at its discretion, may require an inspection of the facility prior to approval of the new license.

(c) The facility shall return to the Department the license issued under the prior name, location, or ownership, immediately upon the change of same, and it shall be considered revoked.

(6) Renewal of License. At least 30 days, but no more than 90 days, prior to the expiration of the license, the facility shall submit an application for license renewal on forms provided by the Department, with the applicable renewal fee.

(a) The Department shall conduct an inspection of the facility prior to renewal of the facility license, to ensure continued compliance with these rules and regulations.

(b) The facility shall be permitted to continue operation under the existing license until such time as the inspection has been completed and the renewal of the annual license is issued or denied.

(c) The renewed annual license shall have an effective date at the date of issue or at the expiration date of the previous license, whichever is later, and shall be effective for twelve (12) months from the effective date.

(7) Denial of License Application or Renewal Application. The Department may refuse to grant a license within the parameters described in “[General Licensing and Enforcement of Licensing Requirements](#)”, Chapter ~~290-1-6~~[111-8-25](#).

(a) The Department may refuse to grant an initial annual license without the requirement of holding a hearing prior to the action.

(b) Denial of an application for a new or renewal license from a facility shall be subject to notice and opportunity for a hearing.

(c) An application may be refused or denied if:

1. The facility has failed to demonstrate compliance with these rules and regulations;

2. The applicant has had a license denied, revoked, or suspended within one year of the date of a new application;

3. The applicant has transferred ownership of a facility within one year of the date of a new application in order to avert denial, suspension, or revocation of a permit; or

4. The applicant has knowingly made any verbal or written false statement of material fact in connection with the application for the license.

(8) Request for Approval for Addition of Services. A facility shall obtain written approval from the Department prior to any addition of services or increase in number of dialysis stations.

(a) At least thirty (30) days prior to the anticipated date of the addition of a new service or an increase in the number of dialysis stations, the facility shall submit a request for approval. The facility shall submit with the request:

~~(1)~~1. A description of any modifications to the facility's physical plant to accommodate the change; and

~~(2)~~2. Evidence that the facility has reviewed staffing availability and added staff positions if indicated to accommodate the change.

(b) The Department may at its discretion conduct an inspection of the facility prior to action on the request for change.

(c) The Department shall notify the facility of the approval of the request for change, or the reason for disapproval. If disapproved, the Department shall indicate the action or information required for approval of the change.

(9) **Notification of the Discontinuation of a Service.** At least thirty (30) days prior to the discontinuation of a facility service, the facility shall notify the Department of the planned discontinuation, and shall provide a description of impact of the change on the care of patients currently served. The facility shall also notify the patients of its planned discontinuation of a facility service.

(10) **Temporary Inactive Status.** If the facility is closing temporarily, and plans to reopen under the same ownership and name, the facility may request to have the license placed on temporary inactive status.

(a) Temporary inactive status shall be granted initially for a period of no more than ninety (90) days, and may be granted upon request for only one additional period of ninety (90) days at the discretion of the Department.

(b) When placed on temporary inactive status, the license shall be returned to the Department, and the facility shall not operate until the license has been reactivated.

(c) The facility shall request in writing that the permit be reactivated at least thirty (30) days prior to the desired date of re-opening. Prior to reactivation of the license, the facility shall be subject to inspection by the Department. If the license is not reactivated within six (6) months, the license shall be considered revoked.

Authority O.C.G.A. Secs. 31-44-2, 31-44-6, 31-44-11. **History.** Original Rule entitled "Application for a License and License Renewal" adopted. F. Dec. 6, 2001; eff. Dec. 26, 2001.

290-9-9111-8-22-.05 Facility Inspections.

(1) The facility shall be available during all hours of operation for observation and examination of the facility and the entirety of its administrative and service operations, by representatives of the Department. If dialyzers are reused for dialysis at the facility, the reprocessing of the dialyzers shall be subject to inspection.

(2) **Initial Inspections.**

_(a) There shall be an initial inspection of a facility prior to the opening date in order to determine that the facility is in compliance with these rules. At the time of the initial inspection the facility shall be ready to operate in compliance with these rules, and shall have available for review:

_1. A copy of the Certificate of Occupancy as required by law;

_2. Written operational policies and procedures for all services described in the application, and for all support and monitoring functions as required by these rules;

_3. Documentation of any agreements with hospitals or other service providers;

_4. Evidence of satisfactory water culture results and water chemical analysis; and

_5. Documentation of qualifications of staff.

_(b) During the period of temporary provisional license, and following the initiation of patient treatment services, the Department shall inspect the facility to determine eligibility for the annual license.

_(3) **Periodic Inspections.** Prior to renewal of the license, and periodically as deemed necessary by the Department, the facility shall be subject to periodic inspections to determine that there is continued compliance with these rules.

_(a) Upon receipt of a complaint alleging a rule violation by the facility, or if the Department has a reason to suspect there has been a rule violation, the facility shall be subject to inspection.

_(b) If the facility is requesting addition of services or dialysis stations, the facility shall be subject to inspection.

_(c) Periodic inspections shall be unannounced.

_(4) **Plans of Correction.** If as a result of an inspection violations of these licensing rules are identified, the facility will be given a written report of the inspection which identifies the rules violated. The facility shall submit to the Department a written plan of correction in response to the report of inspection, which states what the facility will do, and when, to correct each of the violations identified. The plan of correction shall be submitted within ten calendar days of the facility's receipt of the written report of inspection.

Authority O.C.G.A. Sec. 31-44-10. **History.** Original Rule entitled "Facility Inspections" adopted. F. Dec. 6, 2001; eff. Dec. 26, 2001.

290-9-9111-8-22-.06 Facility Organization and Administration.

_(1) Governing Body. The facility shall function under the control of an identifiable governing body, which has full legal authority for the governance and operation of the facility.

_(a) The governing body shall specify in writing the operational objectives of the facility, including which services are to be offered.

_(b) The governing body shall be responsible for the establishment, adoption, and annual review of administrative rules and regulations and facility policies and procedures, and for ensuring that they are in accordance with accepted standards of practice and safeguard the health and safety of patients.

_(c) The governing body shall be responsible for ensuring that the facility's design and operation are in compliance with all relevant federal, state, and local legal requirements.

_(d) The governing body shall adopt for the facility admission criteria that ensure equitable access to services for individuals needing care for end stage renal disease.

_(e) The governing body shall designate sufficient staff and allocate sufficient staff time to implement the facility's quality management program, and shall provide for leadership support of the program.

_(f) The governing body shall establish and implement written policies regarding the determination, selection, or privileging of medical staff for the facility.

_(g) The governing body shall appoint a facility administrator to be responsible for the administrative management of the facility and the enforcement of adopted rules and regulations.

_1. The governing body shall delineate the responsibilities of the facility administrator in writing and shall ensure that the administrator is sufficiently free of other duties to provide effective management of the facility.

_2. The governing body of the facility shall notify the Department of a change in the administrator of the facility, and shall at that time provide the name and contact numbers of the new administrator.

_(2) Facility Administrator.

_(a) The facility administrator may serve on a full-time or part-time basis, but shall serve sufficient time to plan, organize, and direct the overall function of the facility, and to carry out those responsibilities as assigned by the governing body. The facility administrator shall meet one of the following qualifications:

~~(+)~~1. Holds at least a baccalaureate degree and has at least one (1) year experience in an end stage renal disease facility; or

~~(ii)~~2. Meets the qualifications for a physician director or a nurse responsible for nursing services for an end stage renal disease facility as described in these rules; or

~~(iii)~~3. As of the first effective date of these rules, has been acting for at least two years as a facility administrator for an end stage renal disease facility which has been certified for a federal Medicare program.

(b) The facility administrator shall be responsible for:

1. Management of the facility's fiscal affairs, including maintenance of financial records and generating regular reports of expenses and revenues for review by the governing body;

2. Implementing the policies and procedures of the facility as approved by the governing body, and ensuring that all personnel at the facility are familiar with applicable policies as well as applicable state and federal regulations;

3. Coordinating the provision of services at the facility, including establishing clear lines of authority and accountability for those involved in patient care;

4. Ensuring that the facility employs sufficient qualified staff to provide patient care services, and adequately orients staff to their work responsibilities while meeting the following minimum staffing ratios:

(i) There must be one (1) licensed and qualified nurse for every ten (10) patients receiving dialysis care and one qualified dialysis care giver for each four (4) patients present in the immediate clinical care area. At least one licensed and qualified registered nurse shall be available in the immediate clinical care area to provide nursing care whenever patients are being dialyzed.

(ii) Trainees may not be counted in the staff:patient ratios.

5. Maintaining facility records, including a chronological record of patient care services provided, and submitting reports on facility functions and operations as required by the governing body or the Department.

(c) The facility administrator shall serve as the liaison between the governing body and the medical staff and other healthcare workers at the facility.

(d) The facility administrator shall designate in writing a qualified individual to act on his/her behalf in the event of his/her absence.

(e) The facility administrator shall be responsible for ensuring that the care of dialysis patients of the facility is coordinated appropriately when a patient is being transferred to a hospital or another dialysis provider or being received back by the facility.

290-9-9111-8-22-.07 Facility Communication Responsibilities.

(a1) The facility shall develop, adopt, implement, and enforce policies and procedures to ensure that each patient is:

4(a): Provided communication of information in a manner effective for the patient, which may include the services of an interpreter or written form, as appropriate;

2(b) Fully advised of their medical condition in terms that they understand, or, if they are unable to understand, their representative is so advised;

3(c) Informed of all treatment modalities and settings for the treatment of end stage renal disease, and of the criteria for suitability for each treatment modality and setting;

4(d) Informed about, and given the opportunity to participate in, all decisions about care, including the right to refuse treatment and the medical consequences of refusal;

5(e) Informed about all services provided by the facility, the qualifications and training of staff providing services, and the charges for services provided;

6(f) Informed of the facility’s reprocessing of dialyzers or bloodlines, if supplies are reused;

7(g) Transferred or discharged only for medical reasons, for the welfare of the patient, other patients, or staff, or for nonpayment of fees, and given at least thirty (30) days advance notice of the transfer or discharge unless such delay presents significant risk to the patient or others, and that there is documentation of efforts to resolve issues leading to discharge when the discharge is against the patient’s wishes;

8(h) Provided information about, and allowed to formulate, advance directives and have them honored in accordance with current statutes; and

9(i) Informed of the facility’s internal mechanisms for receiving and responding to complaints from patients and others regarding services, and the mechanisms for filing a grievance or complaint against the facility through the licensing agency, without fear of denial of services or retaliation by the facility.

(b2) The facility shall inform each patient upon admission of their responsibilities in the treatment process, and of the facility’s rules regarding patient conduct.

(e3) The facility shall report to the Department whenever any of the following incidents involving patients receiving dialysis services through the facility occurs:

~~1.~~(a) Any unanticipated patient death not related to the natural course of the illness or the patient's underlying condition occurring at the facility or as a direct result of treatment received in the facility;

~~2.~~(b) Any serious injury resulting from the malfunction or intentional or accidental misuse of patient care equipment;

~~3.~~(c) Exsanguination while at the facility;

~~4.~~(d) Any patient dialyzed with another patient's dialyzer where the facility reuses the hemodialyzers;

~~5.~~(e) Any deviation in fulfilling the patient prescription which results in a significant adverse patient outcome;

~~6.~~(f) Any sexual or physical assault of or by a patient which is alleged to have occurred in the facility.

~~(d)~~4 The facility shall make an initial report of the incident within twenty-four (24) hours or by the next business day from when the incident occurred, or from when the facility has reasonable cause to suspect a reportable incident. The initial report shall be received by the Department in confidence, and shall include at least:

~~1.~~(a) The name of the facility;

~~2.~~(b) The date of the incident and that date that the facility became aware that a possible reportable incident may have occurred;

~~3.~~(c) The medical record number(s) of any affected patient(s);

~~4.~~(d) The type of incident suspected, with a brief description of the incident; and

~~5.~~(e) Any immediate corrective action or preventative action taken by the facility to ensure against the replication of the incident prior to the completion of the facility investigation.

~~(e)~~5 The facility is required to conduct an investigation of any of the incidents listed above and to complete and retain on site a written report of the results of the investigation within forty-five (45) days of the discovery of the incident. The complete report of the investigation shall be available to the Department for inspection at the facility, and shall contain at least the following:

~~1.~~(a) An explanation of the circumstances surrounding the incident, including the results of a root cause analysis or other appropriate quality improvement process or tool;

~~2.(b)~~ Any findings and conclusions associated with the review; and

~~3.(c)~~ A summary of any actions taken to correct identified problems associated with the incident, and to reduce the potential for recurrence of the incident.

Authority O.C.G.A. Secs. 31-44-3, 31-5-5, 31-7-131, 31-7-133. **History.** Original Rule entitled “Facility Communication Responsibilities” adopted. F. Dec. 6, 2001; eff. Dec. 26, 2001.

~~290-9-9111-8-22~~.08 Continuous Quality Improvement.

~~(1)~~ Through the facility administration, the medical director, and the medical and nursing staff, the facility shall develop and implement a facility-wide continuous quality improvement program, specific to the facility and designed to perform a systematic, ongoing, concurrent, and comprehensive review of the patient care provided, both in-facility and through the home dialysis program, if provided.

~~(2a)~~ All facility staff shall be involved in the continuous quality improvement program.

~~(b3)~~ Policies and procedures for the continuous quality improvement program shall include the use of a defined methodology for implementation. The methodology selected must include components for measuring the facility’s performance, identifying opportunities for improvement through the use of such quality improvement tools as root cause analyses, setting priorities, and identifying expected outcomes. Reporting mechanisms shall be established, including at least a quarterly review of the continuous quality improvement activities.

~~(e4)~~ The continuous quality improvement program shall continuously monitor at a minimum:

~~4(a):~~ Morbidity and mortality;

~~2.(b)~~ Hemodialyzer reuse, if applicable;

~~3.(c)~~ Water quality;

~~4.(d)~~ Preventable maintenance of facility equipment;

~~5.(e)~~ Clinical outcomes, including but not limited to adequacy of dialysis and anemia management;

~~6.(f)~~ Critical incidents;

~~7.(g)~~ Patient complaints;

~~8.(h)~~ Infection control; and

9(i). Vascular access preservation and complications.

(d5) The results of continuous quality improvement activities and monitoring shall be disseminated to the governing body, the medical director, the medical staff, and any service staff impacted by the results.

(e6) The facility shall take and document remedial action to address service deficiencies identified through the continuous quality improvement program.

Authority O.C.G.A. Sec. 31-44-3. **History.** Original Rule entitled “Continuous Quality Improvement” adopted. F. Dec. 6, 2001; eff. Dec. 26, 2001.

290-9-9111-8-22-.09 Medical Staff and Medical Services.

(1) Medical Director. Any medical director beginning such a function for the first time in Georgia at any facility on or after July 1, 2002 shall be a licensed physician who is board-certified in nephrology. However, a physician who has completed a fellowship in nephrology after July 1, 2002 may direct a dialysis facility in a medically- underserved area for a maximum of two years provided that the physician obtains board certification as a nephrologist by the end of the two-year period. Any physician functioning as a facility medical director at the implementation date of these rules shall be board-eligible or board-certified in nephrology, internal medicine, or pediatrics, and shall have at least one year experience in the care of patients at an end stage renal disease facility.

(a) The medical director shall participate in the development of all patient care policies at the facility.

(b) The facility shall have mechanisms in place for communication of essential patient care issues and information to the medical director.

(c) The medical director shall be responsible for the daily clinical operations of the facility, and for the execution of patient care policies and procedures.

(d) The medical director shall be permitted to provide direct patient care services at the facility, in addition to the duties as the medical director.

(2) Medical Services. The medical director shall ensure that each patient at the facility receives medical care and supervision appropriate to the patient’s dialysis needs.

(a) Each patient shall have an attending physician who is responsible on a continuing basis for the patient’s medical care. Each patient’s records shall clearly indicate the name and contact number for the patient’s physician.

1. The facility shall require a history and physical examination of each patient following admission, prior to the development of the patient’s short-term care plan, and at least annually thereafter.

2. The facility shall require each patient a medical plan of care, prescribed by a physician, to include indicated dialysis or related treatments, dialysis orders, medications, diet, criteria for discharge and any other special services needed.

3. The facility shall require that the patient's physician participates in the development of the long-term and short-term care plans for the patient, and shall assure that the plan for the patient's medical care is based on the assessment of the patient's individual needs.

4. The facility shall require and the medical director shall ensure that the patient's medical progress at the facility is monitored by a physician on-site at least monthly. The facility shall require that each patient have a scheduled opportunity to see a physician at least once per month. Medical patient monitoring and physician visits shall be documented by progress note entries in the patient's medical record.

5. The facility shall require and the medical director shall ensure that any adverse medical patient outcomes are communicated to the patient's physician, and that the facility takes appropriate corrective action.

(b) The medical director shall ensure that there is medical care available at all times for managing emergency situations, for both in-center and home dialysis patients. There shall be posted at each nursing/monitoring station a roster of physicians on-call for the provision of emergency care. The roster shall specify when each physician is available and how they can be reached.

(c) The facility shall ensure that each patient, or each patient's responsible party, is aware of how to access medical care in an emergency, as appropriate to the patient's age and abilities.

Authority O.C.G.A. Sec. 31-44-3. **History.** Original Rule entitled "Medical Staff and Medical Services" adopted. F. Dec. 6, 2001; eff. Dec. 26, 2001.

290-9-9111-8-22.10 Quality Qualifications, Training, and Supervision and Staff Records.

(1) Staff Orientation.

(a) The facility shall provide a facility orientation program for all staff, approved by the medical director, to include at least:

1. A review of the services provided by the facility;

2. A review of facility policies and procedures, including general infection control procedures and use of universal precautions;

3. The facility's emergency procedures and disaster preparedness plans;

Chapter 111-8-22, Proposed Rules for End Stage Renal Disease Facilities
Presented to BCH for Initial Adoption 11/08/12

Page 18 of 51

| _4. The facility's continuous quality improvement program; and

| _5. Documentation and records requirements.

| _ (b) The facility shall document that each staff member has attended the orientation program.

| **_ (2) Nursing Staff.**

| **_ (a) Minimum Education and Experience Qualifications for Nursing Staff.**

| _1. Any registered nurse or licensed practical nurse providing services in the facility shall have and maintain a current Georgia license to practice nursing.

| _2. Registered nurses in charge of the training of patients in self-care, involving either home hemodialysis or peritoneal dialysis, shall have a minimum of three months of experience working with dialysis self-care patients.

| _3. Prior to providing dialysis care, all nursing staff shall demonstrate satisfactory completion of either the training program or educational equivalency and the competency skills assessment checklist as required for dialysis technicians.

| **_ (b) Supervision of Nursing Staff.**

| _1. The nurse responsible for nursing services shall ensure that the licensed practical nurses participating in the provision of appropriate nursing services are familiar with protocols established by the medical staff as necessary for patient care during dialysis treatment. At all times a registered nurse must be in the patient care area while patient care is being provided.

| _2. Any registered nurse or licensed practical nurse who is employed without previous experience in the dialysis process, and who has not yet successfully completed the skills competency checklist, shall be directly supervised when engaged in dialysis treatment activities with patients by a staff member who has demonstrated skills competency for dialysis treatment as required by these rules.

| **_ (c) Training of Nursing Staff.**

| _1. When a facility hires a registered nurse who has not had previous dialysis experience, the facility shall conduct and document a training needs assessment to identify training needs specific to care for the dialysis patient, and shall document the provision of such training by an instructor meeting the qualifications for training dialysis technicians as indicated by the needs assessment, together with satisfactory completion of a skills competency checklist.

2. Licensed practical nurses providing dialysis care shall meet the same training and competency requirements, including the documentation of such training and competency, as required by these rules for dialysis technicians.

3. The facility shall require and maintain adequate documentation for all nursing staff of a minimum of twelve (12) clock hours per year of continuing education related to end stage renal disease treatment.

(d) **Competency Evaluation for Nurses.** The facility shall document for each licensed nurse the satisfactory completion of a skills competency checklist in dialysis treatment, signed by the registered nurse responsible for nursing services at the facility, or qualified instructor under these rules, prior to the unsupervised provision of hemodialysis or peritoneal dialysis treatment to patients and thereafter at least annually. The competency skills assessment shall reflect those patient care activities provided by the nurse, and shall include age-specific competencies when applicable.

(3) Dialysis Technicians.

(a) An individual may not function as or be represented to be a dialysis technician unless that individual has satisfied the training and competency requirements of these rules. The individual in the process of completing training as a dialysis technician shall be identified as a trainee when present in any patient area of the facility.

(b) **Minimum Qualifications for Dialysis Technicians.** Persons first employed by the facility as dialysis technicians after the effective date of these rules shall meet or exceed the following criteria:

1. A high school diploma or equivalent;

2. Documentation of the satisfactory completion of a training program with a curriculum equivalent to or exceeding the curriculum required by these rules for dialysis technicians; and

3. Documentation of the satisfactory completion within the past twelve months of a skills competency checklist equivalent to or exceeding the competencies required by these rules for dialysis technicians, administered at the current employment facility.

(c) Required Training for Dialysis Technicians.

1. A training program curriculum for dialysis technicians shall be approved by the medical director of the facility, and shall include minimally the following educational and clinical components, defined in written form with objectives for each component:

(i) Understanding of the individual with end stage renal disease, to include:

(I) Basic renal anatomy, physiology, and pathophysiology;

- | _ (II) The effect of renal failure on other body systems;
- | _ (III) Signs and symptoms of the uremic state;
- | _ (IV) Basic renal nutrition;
- | _ (V) Basic psychosocial aspects of end stage renal disease; and
- | _ (VI) Medications commonly administered to patients with end stage renal disease, and side effects, toxicity, and other common problems associated with medications;
- | _ (ii) Introduction to dialysis treatments and options including a history of dialysis and definitions and terminologies used;
- | _ (iii) Principles of hemodialysis to include at least:
 - | _ (I) The use of osmosis and diffusion for blood cleaning;
 - | _ (II) Access to the circulatory system; and
 - | _ (III) Anticoagulation and the role of local anesthetics and normal saline;
- | _ (iv) Hemodialysis procedures to include at least:
 - | _ (I) Using aseptic technique;
 - | _ (II) Technical aspects of operation and monitoring of dialysis equipment, and of the initiation and termination of dialysis;
 - | _ (III) Delivery of an adequate dialysis treatment and factors which may result in inadequate treatment;
 - | _ (IV) Observation and reporting of patient reactions to treatment;
 - | _ (V) Glucose monitoring, dialysis adequacy monitoring and hemoglobin/ hematocrit monitoring; and
 - | _ (VI) Emergency procedures and responses such as cardiopulmonary resuscitation, air embolism management, management of hypo and hypertensive crises, response to line separation during hemodialysis, calling an ambulance, and handling patient death;
- | _ (v) Hemodialysis equipment to include at least:
 - | _ (I) Theory and practice of conventional, high efficiency, and high flux dialysis;

- | _ (II) Dialysate composition, options, indications, complications, and safety;
- | _ (III) Safe equipment operation and monitoring; and
- | _ (IV) Equipment disinfection;
- | _ (vi) Water treatment to include:
 - | _ (I) Standards for water treatment used for dialysis as described in the current American National Standard, Hemodialysis Systems, published by the Association for the Advancement of Medical Instrumentation (AAMI);
 - | _ (II) Water treatment systems and devices;
 - | _ (III) Monitoring of water; and
 - | _ (IV) Risks to patients of unsafe water;
- | _ (vii) Reprocessing, if the facility practices dialyzer reuse, to include at least:
 - | _ (I) Principles of reuse;
 - | _ (II) Safety, quality control, universal precautions, and water treatment in reprocessing; and
 - | _ (III) Standards for reprocessing of dialyzers for reuse, as described in the current American National Standard, Reuse of Hemodialyzers, published by the Association for the Advancement of Medical Instrumentation (AAMI);
- | _ (viii) Patient teaching, to include at least the role of the technician in supporting patient education goals;
- | _ (ix) Infection control during dialysis and in the dialysis environment, to include at least:
 - | _ (I) Risks to patients of nosocomial infections, accidents, and errors in treatment;
 - | _ (II) Sterile techniques and specimen handling;
 - | _ (III) Basic bacteriology and epidemiology;
 - | _ (IV) Risks to employees of blood and chemical exposure; and
 - | _ (V) The importance of ongoing quality control activities in assuring safe dialysis treatments are provided to patients;
- | _ (x) The facility's grievance policies, and the handling of patient complaints.

2. If the dialysis technician is to participate in training or treatment with peritoneal dialysis patients, the following components must be included in the training curriculum in addition to those components listed above:

_(i) Principles of peritoneal dialysis;

_(ii) Sterile technique for peritoneal dialysis;

_(iii) Peritoneal dialysis delivery systems;

_(iv) Symptoms of peritonitis; and

_(v) Complications of peritoneal dialysis.

3. If the dialysis technician is to cannulate the access site, the training curriculum shall include, in addition to those components listed under ~~290-9-9111-8-22-.1110(23)~~(c)1. above, training in accessing the circulatory system, including at least:

_(i) The creation and development of a fistula, needle placement for access, and prevention of complications;

_(ii) The materials used and creation of grafts, needle placement for access in a graft, and prevention of complications; and

_(iii) Identification of signs and symptoms of complications when cannulating access.

4. The trainee shall independently complete a written examination at the completion of the training program, which shall encompass the content of the curriculum in subsection 1. of this section, and, as applicable, subsection 2. and/or 3. The trainee shall be required to obtain a passing score of 80% or greater on the written examination. Current certification as a dialysis technician by a nationally recognized certification organization or satisfactory evidence of having successfully passed a nationally standardized test of competency for dialysis care technicians approved by the Department may exempt an individual from the requirement of the training program and written examination, if permitted by facility policy.

5. The curriculum for the training program shall be:

_(i) Reviewed at least annually by the medical director, and updated as needed by changes in the facility's equipment and/or procedures;

_(ii) Administered under conditions that do not compromise the integrity of each individual assessment required for competency tests and the completion of skills checklists; and

_(iii) Where the Department determines that the facility's training program does not appear to provide adequate evidence of training in accordance with these requirements as a result of the identification of rule violations associated with the quality of care being provided by dialysis technicians and/or the facility's performance falls below acceptable levels on at least three patient care quality indicators, such as mortality rate, hospitalization rate, catheter rates, fistula rates, hematocrit levels and urea reduction rates and the Department so notifies the facility, the facility will be required to utilize a nationally standardized competency test approved by the Department. The facility shall have one year from the date of the Department's notification to have all its dialysis care technicians providing care having passed an approved nationally standardized competency test for dialysis care technicians and must continue using the nationally standardized competency test for all new hires. No dialysis care technician hired after the facility has received notice of that nationally standardized competency test is being required by the Department shall be permitted to continue in employment at the facility for more than one (1) year without having satisfactorily completed a nationally standardized test of competency approved by the Department.

6. Instructors. Instructors for the training program for dialysis technicians shall have passed the training and clinic skills competency checklist for dialysis technicians. All instructors providing training for dialysis technicians two years from the effective date of these rules and thereafter, shall have passed a nationally recognized and standardized examination for the provision of dialysis care as approved by the Department.

_(i) For the two years immediately following the adoption of these rules, a registered nurse or licensed practical nurse with at least twelve months of experience in hemodialysis, and at least three months experience in peritoneal dialysis, if applicable to the facility program, or an instructor qualified by education and training providing a dialysis technician training course through an accredited college or university may serve as an instructor of dialysis technicians.

_(ii) **Adjunct Instructors.** With twelve (12) months experience in a dialysis setting, licensed dietitians, licensed social workers or qualified dialysis technicians providing training on water reuse or equipment maintenance may provide those components of the training program within their specific areas of expertise under the supervision of the instructor.

_(d) Clinical Supervision of Dialysis Technicians and Trainees.

_1. Trainees who are in the process of completing a dialysis technician training program shall provide patient care only as a part of the training program, and only under the immediate and direct monitoring of either:

_(i) A licensed nurse meeting the qualifications of this chapter, or

| _ (ii) An assigned preceptor, who is either a licensed practical nurse or a dialysis technician with at least one year of dialysis experience and a current satisfactory skills competency checklist as required of a dialysis technician on file at the facility.

| _ 2. The facility shall define by written policy the hours of directly monitored clinical patient care activities required for the completion of the training program for staff coming into the facility with credentials demonstrating appropriated competencies. At a minimum, facility policy must provide for 40 hours of monitored clinical patient care activities and completion of a skills checklist. For the first forty (40) hours of monitored patient care activities, this staff may not be counted in the staff:patient care ratio.

| _ 3. A licensed facility utilizing a temporary employment agency to provide patient care services must have a written agreement with the temporary agency that specifies that the staff the agency sends to provide patient care services to the facility must meet the staff qualification set forth in these rules. The facility will monitor contract performance to ensure that the agency staff providing patient care services in the facility are competent to perform the assigned patient care tasks and that the agency staff have been familiarized with the particular facility's environment and procedures for handling emergencies prior to caring for patients at the facility.

| _ 4. Dialysis technicians who have completed an acceptable training program and skills competency checklist shall be supervised by a registered nurse. A licensed registered nurse shall be immediately available in the dialysis area to monitor the care being provided by the dialysis technician to the patient.

| _ (e) **Competency Evaluation for Dialysis Technicians.** In addition to the satisfactory completion of the required training program and written examination, the dialysis technician trainee, each dialysis technician newly employed, and each dialysis technician at least annually, shall be required to demonstrate satisfactory clinical patient care performance through a skills competency evaluation.

| _ 1. A licensed nurse who qualifies as an instructor in these rules shall administer to each trainee or technician an assessment of skills through a skills competency checklist which covers at least the following acts:

| _ (i) Assembling necessary supplies for hemodialysis;

| _ (ii) Preparing dialysate according to procedures and dialysis prescription;

| _ (iii) Assembling and preparing the dialysis extracorporeal circuit correctly;

| _ (iv) Securing the correct dialyzer for the specific patient;

| _ (v) Installing and rinsing the dialyzer and all necessary tubing;

| _ (vi) Testing monitors and alarms, conductivity, and (if applicable) presence and absence of residual sterilants;

| _ (vii) Setting monitors and alarms according to facility and manufacturer protocols;

| _ (viii) Obtaining predialysis vital signs, weight, and temperature according to facility protocol and informing the registered nurse of unusual findings;

| _ (ix) Inspecting access for patency and, after cannulation is performed and heparin administered, initiating dialysis according to the patient's prescription, observing universal precautions, and reporting unusual findings to a licensed nurse;

| _ (x) Adjusting blood flow rates according to established protocols and the patient's prescription;

| _ (xi) Calculating and setting the dialysis machine to allow fluid removal rates according to established protocols and the patient's prescription;

| _ (xii) Monitoring the patient and equipment during treatment, responding appropriately to patient needs and machine alarms, and reporting unusual occurrences to a licensed nurse;

| _ (xiii) Monitoring patient blood pressure and taking appropriate actions related to blood pressure according to facility protocol;

| _ (xiv) Documenting findings and actions according to facility protocol;

| _ (xv) Describing indicators and appropriate response to dialysis-related emergencies such as cardiac or respiratory arrest, needle displacement, or infiltration, clotting, blood leaks, or air emboli and to nonmedical emergencies such as power outages or equipment failure;

| _ (xvi) Discontinuing dialysis and establishing hemostasis, to include at least:

| _ (I) Inspecting, cleaning, and dressing the access site according to facility protocol; and

| _ (II) Identifying and reporting unusual findings to a licensed nurse.

| _ (xvii) Obtaining and recording post-dialysis vital signs, temperature, and weight and reporting unusual findings to a licensed nurse;

| _ (xviii) Discarding supplies and sanitizing equipment and treatment chair according to facility protocol;

| _ (xix) Communicating the patient's emotional, medical, psychological, and nutritional concerns to a licensed nurse;

|(xx) Maintaining professional conduct, good communication skills, and attention to privacy and confidentiality during the care of the patient;

|(xxi) For the dialysis technician trainee who will be assisting with training or treatment of peritoneal dialysis patients:

|_(I) Assisting patients in ordering supplies for dialysis;

|_(II) Making a dialysate exchange (draining and refilling the peritoneal space with dialysate) to include continuous ambulatory peritoneal dialysis exchange procedures and initiation or discontinuation of continuous cycling peritoneal dialysis;

|_(III) Observing peritoneal effluent and identifying significant factors;

|_(IV) Collecting dialysate specimen;

|_(V) Performing a transfer tubing change; and

|_(VI) Setting up and operating continuous cycling peritoneal dialysis equipment.

|(xxii) For the dialysis technician trainee who will be cannulating dialysis access, the performance of cannulation, to include:

|_(I) Inspecting the site for access;

|_(II) Preparing the skin;

|_(III) Using aseptic technique;

|_(IV) Placing and securing needles correctly;

|_(V) Establishing blood access;

|_(VI) Replacing needles; and

|_(VII) Recognizing problems and the need to call for assistance; and

|(xxiii) For the licensed practical nurse functioning as a dialysis technician, the skills competency checklist shall include, in addition to the above, the protocols for administering medications and intravenous fluids, including but not limited to normal saline, heparin and subcutaneous lidocaine, during the dialysis treatment.

|_2. For any items failed during the administration of the skills competency checklist, the facility shall document additional training for the trainee or technician in the area(s) of failure, and the trainee or technician shall not be permitted to provide patient care without direct supervision until all checklist items have been demonstrated satisfactorily.

(f) Verification and Demonstration of Completion of the Training Program and Competency Assessment for Dialysis Technicians. When a trainee completes a dialysis technician training program at the facility, the facility shall issue and provide to the dialysis technician a document verifying completion of the training requirements under this chapter. This document may be accepted as proof of completion of training by another facility that later employs the dialysis technician, provided that the dialysis technician is able to satisfactorily complete a skills competency checklist administered by the new place of employment.

(g) Dialysis Acts Permitted for Dialysis Technicians to Perform. A dialysis technician who has successfully completed the training program outlined herein and the skills competency checklist may perform the following actions under the supervision of a licensed registered nurse:

1. Initiate routine dialysis treatments for those patients whom the technicians are not prohibited from dialyzing as outlined in section (h) below.

2. Administer normal saline via the extracorporeal circuit during the initiation and discontinuation of the dialysis treatment and during dialysis treatment according to specified written protocols established by the medical director. At the time that the technician administers normal saline during the course of the dialysis treatment, the technician shall immediately notify the nurse responsible for that patient.

3. Monitor patients during their dialysis treatment and make adjustments in rate of treatment in accordance with established protocols and instructions.

4. Discontinue routine dialysis treatment and establish hemostasis for those patients whom the technician is not prohibited from dialyzing as outlined in section (h) below.

(h) Dialysis Acts Prohibited for the Dialysis Technician. A dialysis technician who is not a licensed practical nurse shall not:

1. Initiate or discontinue hemodialysis via a central catheter, manipulate a central catheter, or change dressings for a central catheter;

2. Administer controlled substances or dangerous drugs to patients at any time, including those medication which may be required during routine dialysis treatment, except for normal saline as provided in paragraph (g)2. above.

3. Administer blood or blood products;

4. Perform non-access site arterial puncture;

5. Accept physician orders; or

6. Provide hemodialysis treatments to pediatric patients under fourteen (14) years of age or under 35 kilograms weight.

4) Reuse Technicians.

(a) Minimum Qualifications for Reuse Technicians. Persons first hired after the effective date of these rules to process kidney dialyzers for reuse at the facility shall meet or exceed the following criteria:

1. A high school diploma or equivalency,

2. Documentation of the satisfactory completion of a training program with a curriculum equivalent to or exceeding the curriculum required by these rules for reuse technicians, and

3. Documentation of the satisfactory completion within the past twelve months of a skills competency checklist equivalent to or exceeding the competencies required by these rules for reuse technicians, administered at the facility where currently employed.

(b) Required Training for Reuse Technicians.

1. A training program curriculum for reuse technicians shall be approved by the medical director of the facility, and shall include minimally the following educational and technical components, defined in written form, with objectives for each component which comply with the American National Standard for Reuse of Hemodialyzers, published by the Association for the Advancement of Medical Instrumentation (AAMI) and herein incorporated by reference:

(i) The basic principles of hemodialysis, emphasizing the role of the dialyzer;

(ii) The rationale for and importance of the use of treated water in dialysis and dialyzer processing, including the risks of using untreated water;

(iii) The facility's protocols for the reprocessing dialyzers and the rationale for each step of the procedure;

(iv) The operation and maintenance of the equipment used by the facility in the reprocessing program;

(v) Infection control procedures; and the importance of infection control in the handling of dialyzers and reprocessing equipment and materials;

(vi) The risks of cross-contamination, and the methods to prevent it;

(vii) The disinfection procedures, including safe handling of disinfectants, cleaning spills and disposing of toxic substances, the importance of protective equipment and

ventilation in the reprocessing area, and the procedures for testing for residual disinfectant in the dialyzer;

_(viii) Documentation procedures and procedures for labeling dialyzers during and after reprocessing; and

_(ix) Criterion for determining when a dialyzer should not be reused, and proper disposal of used dialyzers.

_2. Instructor. An instructor for a reuse technician training program shall be a licensed nurse or trained reuse technician who has successfully completed the skills competency checklist for reuse technicians within the past year.

_3. Prior to completion of the training program and satisfactory demonstration of competency, the reuse technician trainee or newly employed reuse technician shall not engage in any part of dialyzer reprocessing except as a part of the training program and under the direct supervision of an instructor as defined in ~~290-9-9111-8-22~~.10(4)(b)2.

_(c) **Competency Evaluation for the Reuse Technician.** The reuse technician trainee, any newly employed reuse technician, and each reuse technician at least annually, shall be required to demonstrate satisfactory performance of reprocessing tasks through a skills competency evaluation administered by a qualified instructor as defined in ~~290-9-9111-8-22~~.10(4)(b)2.

_1. The competency skills checklist for reuse technicians shall include at least the following:

_(i) Performance of all steps of the facility's protocols for reprocessing dialyzers, including receiving and transporting, rinsing and cleaning, disinfecting, storage, and setup for reuse, and observance of required procedures to control risk of infection and crosscontamination.

_(ii) Monitoring and documentation of air and water quality;

_(iii) Monitoring and documentation of equipment function;

_(iv) Handling of toxic substances and use of protective equipment and clothing, including management of spills;

_(v) Labeling of dialyzers; and

_(vi) Documentation of reprocessing for each dialyzer, and completion of required logs and forms.

_2. For any items failed during the administration of the skills competency checklist, the facility shall document additional training for the trainee or technician in the area(s) of

failure, and the trainee or technician shall not be permitted to reprocess dialyzers without direct supervision until all checklist items have been demonstrated satisfactorily.

(d) Verification and Documentation of Completion of the Training Program and Competency Evaluation for Reuse Technicians. When a trainee completes a reuse technician training program at the facility, the facility medical director shall issue and provide to the reuse technician a document verifying completion of the training requirements under this chapter. This document may be accepted as documentation of completion of training by another facility that later employs the reuse technician, provided that the reuse technician is able to satisfactorily complete a skills competency checklist administered at the new place of employment.

(5) Water Treatment System Technician.

(a) Minimum Qualifications for Water Treatment Systems Technicians. Individuals first hired after the effective date of these rules who are assigned responsibility for the operation and monitoring of the water treatment system shall meet or exceed the following criteria:

1. A high school diploma or equivalency;

2. Documentation of completion of an on-site training program in the principles and fundamentals of water treatment and the operation and maintenance of the equipment currently used by the facility or a training program which covered the same material as provided in the on-site program prior to employment. An on-site training program, if provided, shall be approved by the medical director, and shall include the current standards and procedures for water treatment recommended by the Association for the Advancement of Medical Instrumentation (AAMI), under the title “Hemodialysis Systems”, herein incorporated by reference.

3. Demonstration of an understanding of the risks of patients exposed to water which has not been treated to remove contaminants and impurities, and documentation of satisfactory completion of a skills competency checklist at least annually to include at least the following:

(i) Basic operation and use of the facility’s water treatment system, according to the manufacturer’s protocols, at a minimum, from the water source through the water delivery system;

(ii) Monitoring and testing for water quality and treatment system performance, and documentation of such monitoring, as required by facility protocol;

(iii) Adherence to cleaning and disinfection schedules and procedures for the water treatment equipment;

(iv) Calibration of measurement and monitoring instruments;

| (v) Troubleshooting for equipment malfunctions; and

| (vi) Procedures to be followed if abnormal findings are discovered during water quality monitoring.

| ~~4.(b)~~ All water treatment technicians, regardless of the date of hire must successfully complete a skills competency checklist annually for all water treatment procedures which meets or exceeds the skills competency checklist for new trainees.

| (6) **Equipment Technicians.** An individual first hired after the effective date of these rules who functions as an equipment technician shall have at least the following minimum qualifications:

| (a) High school diploma or equivalency;

| (b) Completion of a training program approved by the medical director of the facility, which includes at least an overview of mechanical and equipment systems at the facility, electrical safety (including lockout) and safety requirements of dialysate delivery systems, standards and protocols for monitoring water bacteriology, both in dialysate and water used for reprocessing;

| (c) Prior to being assigned responsibility for performing any equipment-related maintenance and repairs, the facility must ensure that the technician has completed training in machine maintenance and repairs for the equipment used at the facility for dialysis, reprocessing, and water treatment for which the technician may be responsible for, as provided by the equipment manufacturer(s) or other qualified staff certified by the equipment manufacturer and must complete satisfactorily an appropriate skills competency checklist administered by staff qualified to judge the required job competencies.

| (d) All equipment technicians, whether hired before or after the effective date of these rules, must satisfactorily complete at least annually a skills competency checklist covering all assigned duties administered by staff qualified to judge the required job competencies.

| (7) **Dietitian.** Any dietitian employed by the facility shall hold a current license in the state of Georgia to practice as a dietitian.

| (8) **Social Worker.** The social worker employed by the facility shall hold a current license in the state of Georgia as either a Master's Social Worker or a Licensed Clinical Social Worker.

| (9) **Continuing Education.** Facility staff providing patient care shall attend a minimum of twelve clock hours of continuing education activities related to end stage renal disease and treatment within twelve months of the effective date of these rules and annually

thereafter. Continuing education activities may consist of, but are not limited to, seminars, lectures, and educational workshops or one-on-one training. Continuing education provided at the facility, including technician training programs, shall be accepted toward satisfaction of this requirement. The facility orientation program shall not be accepted for satisfaction of this requirement. Documentation of attendance at continuing education activities shall be kept in the personnel file for each staff member.

(10) Staff Records.

(a) The facility shall compile and maintain a personnel record for each staff member which include documentation of at least:

- 1.** The staff member's employment history;
- 2.** The staff member's job description;
- 3.** The results of annual competency evaluations and job performance evaluations; and
- 4.** Verification of the current status of any professional licenses or certifications, as applicable to the staff member's job functions.

(b) The facility shall maintain for each staff member a record of the evaluation(s) of the staff member's health status.

Authority O.C.G.A. Secs. 31-44-3, 31-44-8, 31-44-9. **History.** Original Rule entitled "Staff Qualifications, Training, and Supervision and Staff Records" adopted. F. Dec. 6, 2001; eff. Dec. 26, 2001.

~~290-9-9111-8-22~~-11 Patient Care Services.

(1) Nursing Services.

(a) Nursing services shall be provided in accordance with current standards of practice as defined by Georgia law.

(b) The facility shall employ a full-time registered nurse to be the nurse responsible for nursing services, and to supervise the provision of patient care by licensed practical nurses and unlicensed personnel.

(c) A licensed registered nurse shall be present in the treatment area when patient treatments are in progress.

(d) The facility shall ensure the following patient care activities are assigned to and performed by appropriately licensed nurses:

- 1.** Conducting nursing assessments on admission and when indicated by an observed or reported change in the patients' health status;

- | _2. Provision of nursing input for the team review of a patient's progress;
- | _3. Recommending to the team changes in treatment suggested by the patient's needs;
- | _4. Administration of medications, including the introduction of intravenous saline;
- | _5. Initiation and discontinuation of hemodialysis via a central catheter, and manipulation of a central catheter or change of dressing for a central catheter;
- | _6. Administration of blood or blood products;
- | _7. The facilitation of communication between the patient, the patient's family, and other members of the treatment team; and
- | _8. Provision of oversight and supervision for dialysis technician trainees, dialysis technicians, and other unlicensed personnel involved in patient care activities, including the recording of treatment observations and interventions in progress notes, as qualified for such oversight and supervision by the rules contained in this chapter.
- | _ (e) Dialysis treatments for pediatric patients under fourteen years of age or under 35 kilograms in weight shall be performed by a licensed registered nurse with experience in pediatric dialysis.
- | _ (2) **Nutrition Services.** The facility shall provide nutrition services to the patients and the patients' families and caregivers, which are designed to maximize the patient's nutritional status. Services shall be provided by a qualified dietitian, as defined by these rules, and shall include at a minimum:
 - | _ (a) Basic nutritional education must be initiated within two weeks of admission by the nursing or dietary staff. A comprehensive nutritional assessment report with recommendations for patient education will be completed within thirty days of admission and at least annually thereafter;
 - | _ (b) Participation as a member of the interdisciplinary treatment team in the development of each patient's plan(s) of care and review of that plan;
 - | _ (c) Availability of a qualified dietitian to provide counseling and assistance to patients during regular treatment times;
 - | _ (d) Recommendations of therapeutic diets specific to each patient's needs, counseling and training for patients related to the dietary recommendations, and monitoring of nutritional status and adherence to dietary requirements by objective and subjective means, with timely intervention when changes are indicated; and

|(e) Regular recording in the patient's medical record of the patient's nutritional status, monitoring data, and progress in meeting nutritional goals.

|(3) **Social Work Services.** The facility shall provide social services which are directed toward supporting and maximizing the patient's social functioning and adjustment to management of end stage renal disease. Services shall be provided by a qualified social worker, as defined by these rules, and shall include at a minimum:

|(a) Psychosocial evaluation of each patient, completed within thirty (30) days of admission and at least annually thereafter;

|(b) Participation as a member of the interdisciplinary treatment team in the development of each patient's plan(s) of care and review of that plan;

|(c) Recommendations regarding changes in treatment which may be indicated by the patient's psychosocial needs;

|(d) The provision of case work and group work services to patients and their families in dealing with the problems and complications associated with end stage renal disease and dialysis;

|(e) Identification of community service agencies and other support resources, and facilitation of patients' access to those resources;

|(f) Provision of access to social work services during times of patient treatment; and

|(g) Regular reporting of the patient's contact with the social worker in the patient's medical record.

|(4) **Laboratory Services.** The facility shall provide or arrange for the laboratory services needed for safe and effective patient treatment.

|(a) If the facility provides its own laboratory services:

_|1. The facility shall have current Georgia licensure and federal certification as required for the tests performed, or a waiver for the tests performed if licensure and certification are not required.

_|2. The facility performing waived tests shall have policies and procedures for obtaining samples, performing tests, and reporting results, which conform to current standards of practice and the manufacturer's specifications.

|(b) If the facility receives services from an outside laboratory, such arrangements shall be made by written contract, which shall ensure that the laboratory meets all applicable state and federal licensing and certification requirements for the tests performed, and which ensures the provision of test results in a timely manner.

_(5) Administration and Storage of Controlled Substances and Dangerous Drugs.

_(a) Controlled substances and dangerous drugs shall be administered to patients only with an order from a licensed physician or from a physician's assistant or nurse practitioner as permitted by Georgia law.

_(b) Controlled substances and dangerous drugs shall be administered to patients only by those persons authorized under Georgia law to administer medications. However, trained and competent dialysis technicians are permitted to administer saline via the extracorporeal circuit as provided under Section ~~290-9-9~~111-8-22-.10(3)(g)2.

_(c) Medications shall be prepared for administration in a work area that prevents contamination during preparation.

_(d) Medications not given immediately shall be labeled with the patient's name, the name of the medication, and the dosage, and the date and time opened, and initialed by the person preparing the medication. All medications shall be administered by the individual who prepares them.

_(e) The facility shall establish and implement procedures for limiting access to medications by unauthorized personnel.

_(f) Medications requiring refrigeration shall be stored in refrigerators used only for that purpose and stored at appropriate temperatures.

_(g) The facility shall regularly inventory controlled substances and dangerous drugs and medication supplies to ensure that outdated supplies are immediately disposed of in an appropriate manner, and that sufficient supplies of usable controlled substances and dangerous drugs are available to meet patient needs.

_(h) Controlled substances shall be stored and dispensed in accordance with the provisions of the Georgia Pharmacy Practice Act and the Georgia Controlled Substance Act.

_(6) Home Training Services for Hemodialysis or Peritoneal Dialysis.

_(a) If the facility provides services for training and support of home dialysis, the facility shall meet the requirements for long and short-term care plans for those patients, to include interdisciplinary conferences.

_(b) In addition to other facility services and support requirements, the facility shall provide for home dialysis patients:

_1. A written outline of the home dialysis training program, including didactic and practice components, including the performance of dialysis treatments by patients and/or

their assisting partner and the requirements for facility surveillance of the patient's home adaptation and water quality, with the requirement that each patient (and their assisting partner, if applicable), satisfactorily complete the training program before beginning home dialysis;

2. Sufficient teaching materials available for patient use during and after home dialysis training;

3. A program for surveillance of the patient's home adaptation, to include an initial visit in the patient's home and subsequent supervisory visits by a licensed registered nurse, as indicated by the patient's medical status and training needs or at least annually, with documentation of all home visits in the patient's medical record;

4. A procedure for continuous re-evaluation of the suitability of home dialysis for the patient, to include evaluation of the adherence of the patient to physician's orders and policies and procedures of the facility, and the adequacy of the dialysis performed in the home;

5. Provision of supplies for the home sufficient to sustain dialysis treatment;

6. Routine transfer set changes, where applicable, for peritoneal dialysis patients at least every six (6) months and as needed;

7. Installation and maintenance of dialysis equipment in the home, including training for the patient in identifying equipment malfunctions and mechanisms for accessing equipment service; and

8. A system for routine monitoring, culturing, and disinfection of the water in the home of each hemodialysis patient, to ensure that the water quality meets the standards recommended by the Association for the Advancement of Medical Instrumentation (AAMI).

(c) The facility shall provide dialysis services at the facility or arrange for the provision of services at a site mutually agreeable to the facility and the patient for the home dialysis patient on those occasions when the home dialysis patient is unable to perform safe and adequate dialysis in the home.

Authority O.C.G.A. Sec. 31-44-3. **History.** Original Rule entitled "Patient Care Services" adopted. F. Dec. 6, 2001; eff. Dec. 26, 2001.

290-9-9111-8-22-.12 Patient Care Plans.

(1) The facility shall coordinate services for each patient through an interdisciplinary treatment team approach. An interdisciplinary treatment team shall be identified at the time of admission for each patient and shall consist of at least:

- | (a) The patient and any family member(s) or other(s) designated as a representative of the patient who wishes to participate and is invited by the patient to participate;
- | (b) Either the patient's attending physician or the medical director of the end stage renal disease facility;
- | (c) A qualified registered nurse, who is responsible for nursing services at the facility;
- | (d) A licensed social worker;
- | (e) A licensed dietitian; and
- | (f) For the long-term care plan, a transplant surgeon or surgeon-designee.
- | (2) There shall be documentation of the participation of the patient (or their representative) in the development and review of the patient's long and short-term plans of care, with consideration given to the patient's preferences. If participation is declined, the declination shall be documented, and there shall be evidence that the content of the plan(s) or decisions were reviewed with the patient or their representative.
- | (3) Long-Term Care Plan. The treatment team shall develop a written, individualized long-term plan of care for each patient, designating a selected treatment modality and a selected setting for treatment.
- | (a) The long-term care plan shall be developed within 30 days of admission to the facility.
- | (b) All suitable treatment modalities shall be considered by the treatment team, regardless of their availability at the current facility, and there shall be consideration of the patient's preferences as well as clinical and psychosocial needs. Transplant status shall be reviewed with each patient quarterly.
- | (c) The long-term care plan for patients deemed unsuitable for transplant shall indicate the specific rationale for the unsuitability.
- | (d) For patients for whom transplant referral has been selected, educational and rehabilitation needs shall be addressed as a part of the long-term care plan.
- | (e) The long-term care plan shall be reviewed and updated at least annually, or sooner if there has been a change in the selected treatment modality or setting.
- | (4) Short-Term Care Plan. The treatment team shall develop a written, individualized, short-term care plan for each patient, defining goals and objectives for treatment in the selected treatment modality. If home dialysis support services are provided by the facility, home dialysis patients shall also have a short-term care plan developed.

|(a) The initial short-term care plan shall be completed within thirty (30) days of admission, based on the medical, psychosocial, and dietary information available on or immediately following admission.

|(b) Goals and objectives for treatment shall be stated in measurable terms. Goals and objectives for the initial short-term care plan shall include, but need not be limited to, completion of needed assessments. Subsequent short-term care plans shall include goals and objectives based on the results from assessments of dietary, psychosocial, medical, and rehabilitation needs.

|(c) The short-term care plan for all patients deemed stable by the interdisciplinary team, including transplant patients, shall be reviewed at least quarterly by the interdisciplinary team, to assess the patient's progress and update the short term care plan to reflect the needs of the patient. Stability shall be determined by written criteria developed by the interdisciplinary team. Plans for unstable patients shall be reviewed monthly as changes in condition require changes in the short-term care plan to ensure that appropriate care is provided.

|(d) Any significant change in the patient's condition, which renders the patient unstable, shall require an immediate notation in the medical record with an updated short-term care plan developed within one week. The notation in the medical record must address any immediate changes that are being made in care to address the change in the patient's condition.

|(e) For home dialysis patients, the short-term care plan shall identify support services to be supplied by the facility, and the frequency with which they are to be provided.
Authority O.C.G.A. Sec. 31-44-3. **History.** Original Rule entitled "Patient Care Plans" adopted. F. Dec. 6, 2001; eff. Dec. 26, 2001.

290-9-9111-8-22-.13 Hemodialyzer Reuse.

|(a) Facilities processing dialyzers for reuse shall adhere to the current American National Standard, Reuse of Hemodialyzers, published by the Association for the Advancement of Medical Instrumentation (AAMI), which are incorporated herein by reference.

|(2) The facility practicing reuse shall provide each patient with information regarding the reuse practice at the facility and an opportunity to ask questions regarding the reprocessing of dialyzers, and shall obtain written informed consent from the patient, or the patient's representative, if applicable, for the use of a reprocessed dialyzer for the patient's hemodialysis.

|(3) The facility shall develop and implement policies and procedures for dialyzer reprocessing which include but are not limited to criteria for determining the safe and useful life of a dialyzer, procedures for documenting the reprocessing history of each

dialyzer, and procedures for documenting maintenance and monitoring of the functioning of the reprocessing equipment. If the facility uses an offsite reprocessing service, the facility shall have policies and procedures regarding the coordination of this service with the handling of dialyzers within the facility, to ensure adequate documentation of the storage and transport of the dialyzers from the time they are removed from the dialysis machine to the time they are returned to the facility.

_(4) The facility shall limit access to the reprocessing room to authorized personnel.

_(5) The reprocessing room shall have a ventilation system, which is connected to an exhaust system vented to the outside, with a fan at the outside end to direct discharge of air outward. The exhaust outlet shall be arranged to minimize recirculation of the exhausted air into the building.

_(6) The system providing water for reprocessing must meet all the requirements for pressure, flow rate, bacteriological and pyrogenic contamination, and other requirements for operating the reprocessing equipment under minimal and peak load conditions.

_(7) If a facility utilizes an off-site reprocessing service, the facility shall be responsible and accountable for the safety and effectiveness of the reprocessing of the dialyzers. Such arrangements must be by written contract requiring that:

_(a) The reprocessing services comply with the American National Standard, Reuse of Hemodialyzers, published by the Association for the Advancement of Medical Instrumentation (AAMI), in its current edition:

_(b) The individuals performing the reprocessing meet training and competency standards equivalent to or exceeding those required for reuse technicians at the end stage renal disease facility;

_(c) The service implements a continuous quality improvement program to monitor the effectiveness and safety of reprocessing procedures;

_(d) There are provisions for transport of the dialyzers to and from the reprocessing site which are adequate to prevent contamination or deterioration; and

_(e) The off-site reprocessing location shall be available during regular business hours for inspection of reprocessing procedures by representatives of the Department.

Authority O.C.G.A. Sec. 31-44-3. **History.** Original Rule entitled "Hemodialyzer Reuse" adopted. F. Dec. 6, 2001; eff. Dec. 26, 2001.

290-9-9111-8-22-.14 Medical Records.

_(1) A current and complete medical record shall be maintained for each patient.

|(2) The facility shall designate a supervisor for the medical records who shall be responsible for the organization, proper documentation, completion and preservation of the facility's medical records.

|(3) The medical records shall be organized in a manner to facilitate the completion and retrieval of information.

|(4) Patients' medical records for the most recent two years shall be kept on site. The remainder of the patient's medical record may be stored off-site if the record is readily available. Medical records shall be retained for at least five years following the date of death or discharge. For pediatric patients, the records shall be retained for three years after the patient reaches the age of majority, or at least five years, whichever is longer.

|(5) Medical records shall be available for inspection only to members of the professional staff, the patient, representatives of the Department acting in an official capacity, or persons authorized in writing by the patient to have access to the medical record.

|(a) The facility shall release copies of all or part of a patient's medical record to an authorized representative of the Department at no cost to the Department when the Department determines that said records are necessary in connection with the Department's licensing and certification responsibilities of a facility.

|(b) The facility shall arrange for the prompt transfer of a courtesy copy of the following parts of the patient's medical record to the receiving facility: the patient's long and short treatment plan, the last two weeks of run sheets and flow charts, a list of current medications, current treatment orders and the last three months of clinical laboratory test results to the receiving facility.

|(c) The facility shall have a mechanism to release copies of all or part of a patient's medical records to the patient or to others with the written consent of the patient or the patient's legal guardian and to others where required by law. The facility may charge a reasonable fee for the copies so produced.

|(d) The medical record for each patient shall contain at a minimum:

|_1. Patient identifying information (name, address, age, sex, marital status);

|_2. Dates of admission, transfer, and discharge, as applicable;

|_3. Names of referring and attending physicians;

|_4. Evaluation and assessment reports, including the history and physical examination administered prior to the initial treatment;

| _5. Reports from any special examinations and consultations, and laboratory and x-ray results;

| _6. Physician's orders;

| _7. Long- and short-term patient care plans;

| _8. Signed consent forms, as applicable;

| _9. Progress notes, including dialysis flow sheets; and

| _10. The discharge summary, including cause of death, if applicable.

| _ (e) All entries in the medical records shall be permanent, accurate, dated with the actual date of entry, and signed by the individual making the entry. Late entries shall be labeled as late entries.

| _ (f) Verbal or telephone orders, if allowed by facility policy, may only be entered by Georgia-licensed personnel, and must be authenticated by the ordering physician or individual taking responsibility for the order at the next patient visit or sooner as required by facility policy.

| _ (g) All medical record entries shall be legible.

| _ (h) Medical records shall be completed within forty-five (45) days after the patient's discharge.

Authority O.C.G.A. Sec. 31-44-3. **History.** Original Rule entitled "Medical Records" adopted. F. Dec. 6, 2001; eff. Dec. 26, 2001.

290-9-9111-8-22-.15 Environment of Care.

| _ (1) **Safety.** The facility shall have sufficient staff, systems and equipment in place to provide a safe environment for patients, staff, and visitors, to include at least:

| _ (a) A system for patients and staff to summon assistance, when needed, from treatment areas and bathrooms;

| _ (b) An incident reporting and monitoring system that promptly identifies, investigates, and takes corrective action regarding all incidents that involve injury to patients or visitors, that involve damage to property, or which have the potential to cause such injury or damage if not corrected;

| _ (c) Policies and procedures to prohibit and prevent verbal or physical abuse or neglect of patients while they are receiving services from the facility;

|(d) A program which requires and documents the inspection, monitoring, and maintenance of biomedical equipment, electrical equipment, and any emergency power systems;

|(e) An environment free of physical hazards such as broken or torn furniture, loose floors or wet flooring, or holes in walls, windows, or ceilings;

|(f) Procedures, supplies, and equipment for the management of biomedical waste and the disposal of sharps in accordance with current accepted standards of practice;

|(g) Adequate supplies of protective equipment for staff involved with patient care; and

|(h) A working telephone on the premises accessible to the patients.

|(2) **Cleanliness and Sanitation.** The facility premises and equipment shall be maintained in a clean and orderly condition. There must be evidence that the facility has systems that satisfactorily address at least the following:

|(a) The description and performance of effective daily, interim, and terminal cleaning routines for all areas;

|(b) Procedures, supplies, and facilities for the management of linens which include separate storage areas and separate transport containers for clean and dirty linens, separate storage areas for patient property if permitted by facility policy, and the requirement that no dirty linens or sanitation equipment shall be stored in a water treatment room or reuse room;

|(c) Clean and orderly storage areas for supplies;

|(d) Facilities and supplies for convenient and effective handwashing throughout the facility, including but not limited to:

|_1. For facilities newly constructed or undergoing major renovation after the effective date of these rules, at least one handwashing sink in the dialysis area for each eight dialysis stations;

|_2. If the facility conducts reuse hemodialysis, a separate handwashing sink in the reuse room;

|_3. If the facility provides on-site peritoneal dialysis, a handwashing sink in the room used for peritoneal dialysis which is separate from any facilities for disposal of effluent (peritoneal dialysis drainage); and

|_4. Hot and cold running water at each sink, with soap or sanitizing solution for washing hands, and clean disposable materials or air dryers for drying hands.

|(e) Sufficient equipment and systems for prevention of infestation by insects, rodents, or other vermin or vectors;

|(f) Systems for the storage and disposal of trash, garbage, and waste in a manner that will not permit the transmission of disease, create a nuisance, or provide a breeding place for insects or rodents; and

|(g) Floor coverings that are intact, with no reservoirs or cracks in the surface where pathogens and standing water may accumulate.

|(3) **Space and Equipment.** The facility shall provide adequate space and equipment to provide the scope of services offered, while ensuring the health and safety of patients and staff.

|(a) For a facility constructed or undergoing renovation after the effective date of these rules, the facility shall have a minimum of 70 square feet of floor space at each treatment station, with the smallest dimension being 7 feet.

|_1. The 70 square feet may include counters, sinks, and aisles.

|_2. There shall be access to both sides of the patient bed/chair at each treatment station, with ease of passage for staff or a wheelchair.

|(b) Public hallways, doorways, and elevators should be of sufficient size so as to accommodate passage of a wheelchair or ambulance gurney or stretcher.

|(c) If the facility provides on-site peritoneal dialysis, there shall be a separate room for the peritoneal dialysis treatment.

|(d) The facility shall have a private area for meetings with patients or family members, separate from the treatment areas.

|(e) The facility shall have an examination room, equipped with a door that closes, an examining table, a readily accessible handwashing sink, and adequate floor space to accommodate the patient's treatment needs.

|(f) If the facility offers services to patients with infectious diseases, the facility shall provide treatment for those patients in accordance with recommendations from the Centers for Disease Control. Some infectious diseases will require the use of isolation rooms and separate dialyzer equipment.

|(g) There shall be sufficient office space for physicians, nurses, social services, administration, and dietetic and other ancillary services to work and meet, physically separated from the patient treatment area(s).

_(h) The facility shall have at least one toilet facility with handwashing sink for patient use, which is accessible for a patient in a wheelchair.

_(4) **Water Treatment System.**

_(a) The facility shall operate a system for the analysis and treatment of water to ensure a continuous water supply sufficient in quantity and quality to conduct dialysis in accordance with accepted standards of practice.

__1. Responsibility for the effective operation of the water treatment system shall be assigned to the medical director of the facility.

__2. Policies and procedures shall be developed and implemented to govern all staff actions relative to water treatment; and

__3. Systems for water treatment, water monitoring, water delivery, and water disposal shall adhere to the current standards for water treatment as described in the American National Standard, “Hemodialysis Systems”, published by the Association for the Advancement of Medical Instrumentation (AAMI), herein incorporated by reference.

_(b) The area used for water treatment shall be separate from the area(s) used for dialysis treatment, dialyzer reprocessing, or other activities and purposes at the facility. Mixing of dialysate may be performed in the area used for water treatment, if there is sufficient space for both functions.

_(c) The facility’s water treatment system shall be continuously monitored during patient treatment, and shall be equipped with a functional audible and visible alarm system to alert staff if there is a failure of the system.

_(d) Staff assigned to the operation and monitoring of the water treatment system shall meet the training and competency qualifications for water treatment technicians required under this chapter.

_(e) Staff shall maintain a written log of the operation of the water treatment system throughout each treatment day. Entries into the log shall be current and legible, and shall indicate that each component of the system is operating within required parameters or shall describe actions taken when operation is outside required parameters.

_(f) Monthly testing of product water from selected sample sites within the system shall be conducted to assess compliance with AAMI water quality standards. In addition, a sample of product water shall be submitted for chemical analysis every six months, or sooner if there have been changes to the system or if the monthly results indicate there may have been a significant change in quality. Reports of all water testing shall be reviewed and signed by the medical director.

Authority O.C.G.A. Sec. 31-44-3. **History.** Original Rule entitled “Environment of Care” adopted. F. Dec. 6, 2001; eff. Dec. 26, 2001.

290-9-9111-8-22-.16 Infection Control.

_(1) The facility shall have an infection control committee composed of at least the facility administrator, a physician, and a registered nurse. The infection control committee shall develop and implement policies and procedures for preventing and controlling hepatitis and other infections at the facility, including but not limited to:

_(a) Operational procedures for the prevention of the spread of infectious diseases, including identification of job classifications or work areas or tasks requiring the use of protective barriers and other universal precautions as recommended by the Centers for Disease Control;

_(b) Procedures for facility-wide surveillance and reporting of infections, to include mechanisms for tracking infection rates and suspected pyrogenic reactions;

_(c) Procedures for the safe handling of waste and contaminants, including the safe disposal of sharps;

_(d) Specific procedures for the sterilization and disinfection of equipment, including dialysis machines;

_(e) Procedures for maintaining a safe and clean physical environment;

_(f) Procedures for the prevention of contamination by blood and other body fluids of facility areas outside the dialysis and dialyzer reprocessing areas;

_(g) Procedures for prevention of cross-contamination in storage and treatment areas and in the dialyzer reprocessing area, if applicable;

_(h) Procedures for providing dialysis for patients testing positive for hepatitis B surface antigen or other bloodborne infectious diseases as outlined by the CDC in its current guidelines for infection control in dialysis centers, including reservation or special disinfection of dialysis equipment;

_(i) Procedures for providing dialysis for patients with active pulmonary tuberculosis or other active airborne infectious disease;

_(j) Procedures for the protection of patient clothing, blankets, or other personal articles during the time when blood lines are opened or needles inserted or withdrawn; and

_(k) Procedures for the investigation of infections.

_(2) Reports of infections such as bacteremia, septicemia, hepatitis, any wound that may allow for cross-contamination of patients and any suspected pyrogenic reactions and

other communicable diseases of patients shall be made to the infection control committee through established mechanisms, and noted in patient files. Reports maintained by the infection control committee shall include documentation of efforts to determine the origin of the infection, and, where the dialysis procedure or environment was found to be related to the transmission of the infection, shall include documentation of the actions taken to prevent recurrence.

(3) Facility policies and procedures shall require that all employees be tested upon employment and that attending physicians and physician extenders, be tested at the time privileges are granted for hepatitis B virus and tuberculosis infection and any other infectious diseases which the Centers for Disease Control have deemed to be endemic to the area served. The facility policy and procedures shall also require all employees, attending physicians and physician extenders to be tested for the diseases listed herein at least annually and when the health and safety of the patients require it. The facility shall have a mechanism for monitoring the health status of employees and referring for health evaluations and treatments as necessary to ensure the safety of patients.

(4) Dialysis patients shall be tested initially and at least annually for the presence of Hepatitis B surface antigen, and for tuberculosis and any other infectious diseases which the Centers for Disease Control have deemed to be endemic to the area served, to determine the need for special treatment precautions and surveillance of the infection. Results of the screenings, as well as any refusals to submit to such testing signed by the patient, shall be included in the patient's medical record.

Authority O.C.G.A. Sec. 31-44-3. **History.** Original Rule entitled "Infection Control" adopted. F. Dec. 6, 2001; eff. Dec. 26, 2001.

290-9-9111-8-22.17 Emergency and Disaster Preparedness.

(1) The facility shall establish and implement procedures that describe staff and patient actions in medical and non-medical emergencies, including at least fire, equipment failure, power outages, medical emergencies, unscheduled facility closing, and natural disasters which are likely to threaten the health and safety of patients or staff.

(2) The facility shall provide training for staff and patients in where to go, what to do, and whom to contact if a medical or non-medical emergency occurs. Patient training in the handling of emergencies shall be documented in the patient's medical record and review with the patient at least annually.

(3) The facility plan shall include method of access to community emergency services. Contact numbers for emergency needs, shall be conspicuously posted near a telephone readily available to the clinical treatment area.

(4) The facility shall have and maintain appropriate equipment and supplies, in ready-to-operate condition, for managing medical emergencies, in a location accessible by all

healthcare personnel. By October 1, 2002, all licensed facilities shall have an automatic external defibrillator. Emergency trays or carts shall include at least:

_(a) Emergency drugs and supplies for administering treatment;

_(b) Oxygen or compressed air for respiratory support;

_(c) Equipment for mechanical assistance with ventilation; and

_(d) Oral airway access-devices and suctioning equipment.

_(5) The facility shall establish and implement a plan for management of staff and patients in the event of a fire and provide for patient education on emergency evacuation.

_(a) Evacuation routes shall be posted in all treatment areas, and patients shall be informed of these routes.

_(b) The facility shall conduct and document regular fire and/or disaster drills for all shifts of service provision. Fire and/or disaster drills shall be conducted at least every six months.

_(c) The facility shall have and maintain operable fire extinguishers adequate for the space and conditions.

_(d) All facility staff shall be trained in the operation of emergency equipment, as appropriate to their qualifications and licensure.

_(e) All staff shall be knowledgeable of emergency procedures and their role in the event of an emergency or disaster situation.

_(f) All personnel at the facility who provide direct healthcare services for patients must maintain current certification in Basic Cardiopulmonary Life Support (BCLS) and the use of the automatic external defibrillator when the facility acquires one.

_(g) The facility shall prepare a plan for procedures in the event of a natural or other disaster which may affect the facility's ability to provide patient treatment.

_1. The disaster preparedness plan shall include at a minimum plans for the following emergency situations:

_(i) Local or widespread weather emergencies or natural disasters, such as tornadoes, hurricanes, earthquakes, ice or snow storms, or floods;

_(ii) Unanticipated interruption of service of utilities, including water, gas, or electricity, either within the facility or within a local or widespread area;

(iii) Loss of heat or air conditioning;

(iv) Fire, explosion, or other physical damage to the facility.

2. The facility shall have a written agreement with at least one other licensed facility that can provide dialysis services, to assure that the facility's patients will be treated in the event that an emergency situation at the facility renders it unable to provide scheduled dialysis services.

3. The facility shall have an emergency lighting system sufficient to allow for safe discontinuation of treatments and evacuation of the facility in the event of power failure.

4. The facility's disaster preparedness plan shall be made available to the Department for inspection upon request.

Authority O.C.G.A. Sec. 31-44-3. **History.** Original Rule entitled "Emergency and Disaster Preparedness" adopted. F. Dec. 6, 2001; eff. Dec. 26, 2001.

290-9-9111-8-22-.18 Requests for Waiver or Variance.

(1) A facility may request a waiver or variance of a specific rule by application on forms provided by the Department.

(a2) The Department may grant or deny the request for waiver or variance at its discretion. If the waiver or variance is granted, the Department may establish conditions, which must be met by the facility in order to operate under the waiver or variance. Waivers or variances may be granted with consideration of the following:

1.(a) **Variance.** A variance may be granted by the Department upon a showing by the applicant that the particular rule or regulation that is the subject of the variance request should not be applied as written because strict application would cause undue hardship. The applicant must also show that adequate standards exist for affording protection for the health, safety, and care of patients, and these existing standards would be met in lieu of the exact requirements of the rule or regulation.

2.(b) **Waiver.** The Department may dispense altogether with the enforcement of a rule or regulation by granting a waiver, upon a showing by the applicant that the purpose of the rule or regulation is met through equivalent standards affording equivalent protection for the health, safety, and care of the patients.

3.(3) **-Experimental Waiver or Variance.** The Department may grant a waiver or variance to allow experimentation and demonstration of new and innovative approaches to delivery of services, upon a showing by the applicant that the intended protections afforded by the rule or regulation in question are met and that the innovative approach has the potential to improve service delivery.

(b4) Waivers and variances granted by the Department shall be for a time certain, as

determined by the Department.

Authority O.C.G.A. Sec. 31-2-~~47~~. **History.** Original Rule entitled “Requests for Waiver or Variance” adopted. F. Dec. 6, 2001; eff. Dec. 26, 2001.

290-9-9111-8-22.19 Enforcement of Rules and Regulations.

(1) An end stage renal disease facility that fails to comply with these rules and regulations shall be subject to sanctions and/or license revocation as provided by law.

(a2) The Department may take actions to enforce these rules and regulations as prescribed in the Rules and Regulations for General Enforcement of Licensing and Enforcement Requirements, Chapter 290-1-6111-8-25, pursuant to O.C.G.A. Sec. 31-2-68, and/or by appointment of a temporary manager as described in these rules.

(b3) **Voluntary Appointment of a Temporary Manager.** A person holding a controlling interest in an end stage renal disease facility may, at any time, request the Department to assume the management of the facility through the appointment of a temporary manager.

1(a) If the Department considers the appointment appropriate for the protection of the health and safety of patients, the Department may enter into an agreement providing for the appointment of the temporary manager to manage the facility under conditions agreed upon by both parties.

(i)1. The agreement shall specify all terms and conditions of the temporary manager’s appointment and authority.

(i)2. The agreement shall preserve all rights granted by law to patients of the facility.

2(b). The primary duty of the temporary manager shall be to ensure that adequate and safe services are provided to patients until temporary management ceases.

3(c). The appointment shall terminate at the time specified by the agreement.

(b4) **Involuntary Appointment of a Temporary Manager.** The Department may request that the state Attorney General bring an action for the appointment of a temporary manager to manage the facility, if:

1(a)- The facility is operating without a license;

2(b) The Department has denied, suspended, or revoked the facility’s license but the facility continues to operate;

3(c) License denial, suspension, or revocation proceedings against the facility are pending and the Department determines that there exists an imminent or reasonable foreseeable threat to the health and safety of a patient of the facility;

~~4~~(d) The Department determines that an emergency exists that presents an immediate threat to the health and safety of a patient of the facility; or

~~5~~(e) The facility is closing and arrangements for the care of patients by other licensed facilities have not been made before closure.

~~(e)~~5 A temporary manager appointed under either voluntary or involuntary condition shall be entitled to a reasonable fee as determined by the court. The fee shall be paid by the facility.

~~(d)~~6 A temporary manager appointed voluntarily may petition the court to order the release of any payment owed to him/her for care and services provided to patients at the facility if the payment has been withheld before or during the period of appointment, including any Medicaid, Medicare, or insurance payment, or payment from another third party.

Authority O.C.G.A. Secs. 31-2-~~68~~, 31-44-13 et seq. **History.** Original Rule entitled “Enforcemnt of Rules and Regulations” adopted. F. Dec. 6, 2001; eff. Dec. 26, 2001.

290-9-9111-8-22-.20 Severability of These Rules.

In the event that any rule, sentence, clause or phrase of any of these rules and regulations may be construed by any court or competent jurisdiction to be invalid, illegal, unconstitutional, or otherwise unenforceable, such determination or adjudication shall in no manner affect the remaining rules or portions thereof. The remaining rule or portions of rules shall remain in full force and effect, as if such rule or portions thereof so determined, declared, or adjudged invalid or unconstitutional were not originally a part of these rules.

Authority O.C.G.A. Secs. 31-2-4, 31-2-7, and 31-44-1 et seq. **History.** Original Rule entitled “Severability of These Rules” adopted. F. Dec. 6, 2001; eff. Dec. 26, 2001.